GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:647
ANSWERED ON:21.11.2001
GUIDELINES FOR RESEARCH INSTITUTIONS
KANTI SINGH;MOHAMMED SHAHABUDDIN

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether the Government have issued any circular making it mandatory for all research institutions to follow the guidelines proposed by the Indian Council of Medical Research 20 years ago;

(b) whether these guidelines are not being followed by the Drug Manufacturers in the country having some lacuna and effective control of the guidelines;

(c) if so, the details thereof;

(d) whether the Government propose to revise these guidelines to make them more effective; and

(e) if so, the details thereof?

Answer

THE MINISTER OF HEALTH AND FAMILY WELFARE (DR. C.P. THAKUR)

(a)to(e): Ethical guidelines for bio-medical research on human subjects prepared by the Indian Council of Medical Research (ICMR) in the year 1980 were revised and published in the year 2000 in view of the current advances in science and technology.

All applicants for approval of clinical trials for new drugs are being specifically advised by the Office of DCG (I) to follow these revised guidelines.